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| EXAMINER |
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FRONDA, CHRISTIAN L

| ART UNIT | PAPER NUMBER |
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1652

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/712,391

Applicant(s)

PIER ET AL.

Examiner

Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13-18, 27, 34, 42, 49, 53, 63, 69-71, 73, 84, 90, 96, 97, 107 and 116 is/are pending in the application.
4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 63 and 69-71 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 12 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/04, 5/05, 7/05, 12/05, 3/6/06, 3/13/06, 5/06
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-10,13-18,27,34,42,49,53,73,84,90,96,97,107 and 116.

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DETAILED ACTION

1. Applicant's election with traverse of Group VII in the reply filed on 07/19/2006 is acknowledged. The traversal is on the grounds that a search and examination of multiple Groups would not present an undue burden. This is not found persuasive. A search of all the inventions in the patent literature and the non-patent literature cannot be made without serious burden because the inventions require separate searches that have different limits, boundaries, scope, and subject matter. Because these inventions are distinct for these reasons and the reasons of record and have acquired a separate status in the art as shown by their divergent subject matter and classification, restriction for examination purposes is proper. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-10, 13-18, 27, 34, 42, 49, 53, 73, 84, 90, 96, 97, 107 and 116 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

2. Claims 63 and 69-71 are under consideration in this Office Action.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 63 and 69-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 63 is vague and indefinite for reciting the phrase "An isolated nucleic acid molecule, comprising (a) nucleic acid molecules". It is uncertain how the claimed isolated nucleic acid molecule can comprise more than one nucleic acid molecule. It is unclear if applicants actually intended to recite an isolated nucleic acid molecule comprising a nucleotide sequence that hybridizes under stringent conditions to SEQ ID NO: 2".

In claims 63 and 71 the phrase "enhance production of a polysaccharide from an *ica* locus" renders the claim vague and indefinite. The term "enhance" is not defined by the claim,

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the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. The phrase "*ica* locus" is vague and indefinite because the specific nucleotide sequence and structure and the encoded proteins and/or enzymes have not been defined and recited in the claim. Thus, no patentable weight is given to this phrase.

Claims 69 and 70 which depend from claim 63 are also rejected because they do not correct the defect of claim 63.

Claim 69 is vague and indefinite for reciting the phrase "*ica* locus" because the specific nucleotide sequence and structure and the encoded proteins and/or enzymes have not been defined and recited in the claim. Thus, no patentable weight is given to this phrase.

Claim 71 is vague and indefinite for reciting the phrase "fragment spans a MN8n mutation and enhances production of a polysaccharide from an *ica* locus". The metes and bounds of the phrase are not clear since the specific mutation has not been defined in the claim or in the specification. The phrase "*ica* locus" is vague and indefinite because the specific nucleotide sequence and structure and the encoded proteins and/or enzymes have not been defined and recited in the claim. Thus, no patentable weight is given to this phrase.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 63 and 69-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or

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unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claim 63 encompasses any isolated nucleotide molecule that hybridizes to any part of SEQ ID NO: 2 and has any addition, deletion, or substitution in any region between and including nucleotides 9-43 of SEQ ID NO: 2 or complements thereof which have any biological function. The specification provides guidance and working examples for the nucleotide sequence of SEQ ID NO: 2. However, the specification does not provide guidance, prediction, and working examples for making any isolated nucleotide molecule that hybridizes to any part of SEQ ID NO: 2 and has any addition, deletion, or substitution in any region between and including nucleotides 9-43 of SEQ ID NO: 2 of any biological function.

Thus, an undue amount of trial and error experimentation must be preformed where such experimentation involves searching and screening a vast number of biological sources for any isolated nucleotide molecule that hybridizes to any part of SEQ ID NO: 2 and has any addition, deletion, or substitution in any region between and including nucleotides 9-43 of SEQ ID NO: 2 and determining its biological function. Alternatively, trial and error experimentation encompasses searching and screening for specific nucleotides in SEQ ID NO: 2 to change (e.g., nucleotide addition, deletion, substitution, and combinations thereof) to make the claimed polynucleotide and determining its biological function. General teaching regarding screening and searching for the claimed invention is not guidance for making the claimed invention.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific nucleotides in SEQ ID NO: 2 to change and its specific biological function. Without such a guidance, the amount of experimentation left to those skilled in the art to make the invention is undue and well outside of routine experimentation.

Furthermore, with regard to claim 63, directed to a polynucleotide sequence that hybridizes to the disclosed sequence of SEQ ID NO: 2, applicants have not sufficiently defined the conditions under which the hybridizations are to take place. Nucleic acid hybridization assays are extremely sensitive to the conditions in which they are performed. The buffer composition, pH, temperature, length of time, salt concentrations, quality and source of template nucleic acid, are all variables which determine the reproducibility of a given hybridization experiment. Given the unpredictability of the art and the nature of hybridization experiments in general, it is not sufficient to merely cite hybridization without a clear and explicit recitation of the conditions associated with the hybridization. For example, the definition of stringency as it pertains to hybridization conditions is subject to interpretation and is different from laboratory to laboratory.

Therefore, without a clear and explicit recitation of the conditions which were actually used by Applicants in isolating the claimed polynucleotides which hybridize to the disclosed sequence, the skilled artisan would not be able to practice the claimed invention and would not be reasonably apprised of the metes and bounds of the claimed invention. Without such guidance, the experimentation left to those skilled in the art is undue. Including in the claims the

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exact nature of the hybridization conditions used to isolate the claimed polynucleotides would aid in overcoming this portion of the rejection.

Claims 69 and 70 which depend from claim 63 are also rejected because they do not correct the defect of claim 63.

The nature and breadth of the claim 71 encompasses any isolated fragment of SEQ ID NO: 1 or complement thereof which have any biological function. The specification provides guidance and working examples for the nucleotide sequence of SEQ ID NO: 1. However, the specification does not provide guidance, prediction, and working examples for any isolated fragment of SEQ ID NO: 1 or complement thereof which have any biological function.

Thus, an undue amount of trial and error experimentation must be preformed where such experimentation involves searching and screening a vast number of biological sources for any isolated fragment of SEQ ID NO: 1 or complement thereof and determining its biological function. Alternatively, trial and error experimentation encompasses searching and screening for fragments of SEQ ID NO: 1 and determining its biological function. General teaching regarding screening and searching for the claimed invention is not guidance for making the claimed invention.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific biological function of the fragments of SEQ ID NO: 1 or complements thereof. Without such a guidance, the amount of experimentation left to those skilled in the art to make and/or use the invention is undue and well outside of routine experimentation.

8. Claims 63 and 69-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 63 is a genus claim that is directed toward a genus of nucleotide molecules that hybridize to any part of SEQ ID NO: 2 and has any addition, deletion, or substitution in any region between and including nucleotides 9-43 of SEQ ID NO: 2 or complements thereof which have any biological function. The scope of the each genus includes many members with widely differing structural, chemical, biological, and physical characteristics. Furthermore, the each genus is highly variable because a significant number of structural differences between genus members exist.

Claim 71 is a genus claim that is directed toward a genus of isolated fragments of SEQ ID NO: 1 or complement thereof which have any biological function. The scope of the each genus

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includes many members with widely differing structural, chemical, biological, and physical characteristics. Furthermore, the each genus is highly variable because a significant number of structural differences between genus members exist.

The specification discloses an isolated polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 2 and an isolated polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 1. However, the claims do not recite a particular structure to function relationship which would be common to the members of each genus. Furthermore, the specification does not provide evidence of any description of a structure to function or activity relationship which would be expected to be common to the members of the genus and would distinguish members of the genus from other polynucleotides

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definitions, such as the structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe the genus of genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g. structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. Therefore, the instant claims are not adequately described.

In view of the above considerations, one of skill in the art would not recognize that applicant was in possession of a genus nucleotide molecules that hybridize to any part of SEQ ID NO: 2 and has any addition, deletion, or substitution in any region between and including nucleotides 9-43 of SEQ ID NO: 2 or complements thereof which have any biological function, and a genus of isolated fragments of SEQ ID NO: 1 or complement thereof which have any biological function.

Claims 69 and 70 which depend from claim 63 are also rejected because they do not correct the defect of claim 63.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 63, 69, and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Pier et al. (Accession AAZ87998. 31-MAY-2000; and WO 00/03745. 27 January 2000).

Pier et al. teach an isolated nucleic acid molecule that is expected to hybridize to SEQ ID NO: 2 under stringent conditions because of the nucleotide similarity of 86.7% identity to SEQ ID NO: 2, where the said isolated nucleic acid molecule has an addition, deletion, or substitution of a nucleotide in a region including nucleotides 9-43 of SEQ ID NO: 2 (see attached Alignment to SEQ ID NO: 2).

WO 00/03745 teaches that the said isolated nucleic acid molecule can be placed in a vector and the vector transformed in a host cell (see pps. 40-44). Thus, the reference teachings anticipate the claims.

11. Claim 71 is rejected under 35 U.S.C. 102(b) as being anticipated by Cramton et al. (Accession AF086783. 01-OCT-1999).

Because claim 71 recites "a nucleic acid molecule having a sequence of SEQ ID NO: 1", then the claim encompasses any polynucleotide comprising any fragment of SEQ ID NO: 1 and any complement of any fragment of SEQ ID NO: 1.

Cramton et al. teach a polynucleotide comprising a fragment of SEQ ID NO: 1 (see attached Alignment to SEQ ID NO: 1). Since Cramton et al. teach the sense strand of a polynucleotide comprising a fragment of SEQ ID NO: 1, then Cramton et al. also inherently disclose the complement of the said polynucleotide. Thus, the reference teachings anticipate the claim.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday- Friday from 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N.

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Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CLF


TEKCHAND SAIDHA
PRIMARY EXAMINER